JUN - 6 2003

Medtronic Sofamor Danek CABLE REDUCTION SYSTEM
510(k) Summary (K030816)
May 2003

I. **Company:** Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proposed Proprietary Trade Name:**

MSD CABLE REDUCTION SYSTEM

Regulation Numbers: 888.3050 and 888.3010

Regulation Names: Bone Fixation Cerclage, Spinal Interlaminal Fixation Orthosis

Codes: KWP, JDQ

III. **Description**

The MSD CABLE REDUCTION SYSTEM is a temporary implant for the use in orthopaedic surgery. The system is intended to help provide temporary stabilization, augment the development of solid bony fusion and/or aid in the repair of bone fractures.

The system consists of a multi-stranded cable and ancillary components used in several different configurations. The MSD CABLE REDUCTION SYSTEM implant components are made of medical grade stainless steel described by ASTM Standard F-138 or ISO 5832-1 or ISO 5832-9. Alternatively, the system may be made out of titanium alloy or titanium, as described in ASTM F-136 or ISO 5832-3 for the surgical grade titanium alloy and ASTM F 67 or ISO 5832-2 for pure titanium. The MSD CABLE REDUCTION SYSTEM may be sold sterile or non-sterile.

IV. **Indications for Use:**

The MSD CABLE REDUCTION SYSTEM screws and hooks are only intended for use in the thoracic and lumbar spine. The system provides an alternative to sublaminar and intraspinous process wiring for trauma applications. Another application is the use of the MSD CABLE REDUCTION SYSTEM for instrumentation involved in the correction of scoliotic, kyphotic, and lordotic deformities. The system may also be used with other

spinal implants such as the MSD Unit Rod, the ATLAS™ CABLE System or the Luque Rod, or wherever "wiring" may help secure the attachment of other implants.

V. Substantial Equivalence:

The subject MSD CABLE REDUCTION SYSTEM components were declared substantially equivalent to the predicate ATLAS™ CABLE System components manufactured by Medtronic Sofamor Danek.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Dr. Richard Treharne, Ph.D.
Senior Vice President, Regulatory Affairs
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K030816
Trade Name: MSD Cable Reduction System
Regulation Number: 21 CFR 888.3050, 888.3010
Regulation Name: Spinal interlaminal fixation orthosis, Bone fixation cerclage
Regulatory Class: II
Product Code: KWP, JDQ
Dated: April 21, 2003
Received: April 22, 2003

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030816

Device Name: MSD CABLE REDUCTION System

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(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use _____ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)
(Optional 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030816